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MAY 0 8 2013

510(k) Summary

Submitter's Name and Address:	Scion Medical Technologies, LLC 90 Oak Street Newton, MA 02464 U.S.A.
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Date Prepared:	**7 May 2013**
Proprietary Name(s):	**Beacon Tissue Marker™**
Common Name:	**Implantable Clip**
Classification Panel	**General and Plastic Surgery**
Classification of Device:	**Class II, 21 CFR 878.4300**
Product Code:	**NEU**

Predicate Devices:			
	KMD-Mark1 Tissue Marker	K093473	July 02, 2010
	BiomarC® Tissue Marker	K063193	November 21, 2006

Device Description:	The proposed Beacon Tissue Marker consists of a radiographic soft tissue marker and the delivery system. The proposed Beacon Tissue Marker is a sterile, single patient use, PEKK discrete marker that is visible on standard radiographs (x-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI) at up to 3.0 Tesla field strength. The proposed Beacon Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. The proposed Beacon Tissue Marker is comprised of Oxford Performance Materials (OPM) OXPEKK-IG200 filled with Barium

	Sulfate (Polyetherketoneketone with 20% $BaSO_4$ by wt%). OXPEKK-IG200 is a radiolucent material and serves as the carrier for the radiopaque $BaSO_4$. The proposed Beacon Tissue Marker delivery system is a distal delivery needle tip, rigid shaft, sterile, and single patient use pre-loaded delivery system incorporating the Beacon Tissue Marker. The delivery system consists of a cannula with a handle, a push rod with a plunger, and an end cap. The tissue marker is retained within the delivery system until placement is desired, where it is delivered through the end port by fully depressing the plunger into the handle. The Beacon Tissue Marker delivery system is used to place the Beacon Tissue Marker into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. The delivery system device has a beveled 12 cm / 14 gauge needle with 1 cm depth marks and a plunger.
Indications for Use:	The Beacon Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.
Technological Characteristics:	The purpose of this premarket notification is to seek clearance for a device modification to the Kent Medical Devices, Inc. KMD-Mark1 Tissue Marker (K093473, cleared on July 02, 2010), specifically for the modification of the already cleared and unchanged KMD-Mark1 soft tissue marker (K093473, cleared on July 02, 2010) to be inserted into the already cleared and currently marketed BiomarC tissue marker delivery system (K063193, cleared on November 21, 2006). The modified device will be marketed by Scion Medical Technologies, LLC under the trade name Beacon Tissue Marker.
Conclusion:	In summary, Scion Medical Technologies, LLC believes that the proposed Beacon Tissue Marker, as described in this submission, does not raise any new or significant questions of safety and efficacy and is substantially equivalent to the predicate Kent Medical Devices, Inc. KMD-Mark1 Tissue Marker (K093473), which was determined to be substantially equivalent and cleared on July 02, 2010, and the predicate Carbon Medical Technologies, Inc. BiomarC Tissue Marker (K063193), which was determined to be substantially equivalent and cleared on November 21, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Scion Medical Technologies LLC
% Ostendorf Consulting
Mr. Joseph Ostendorf
23879 Blue Spruce Road
Sauk Centre, Minnesota 56378

May 8, 2013

Re: K130763
Trade/Device Name: Beacon Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 03, 2013
Received: April 08, 2013

Dear Mr. Ostendorf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130763

Device Name:

Beacon Tissue Marker™

Indications For Use:

The Beacon Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130763